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OFFICE OF PETITIONS

In re Patent No. 7,544,768	:	DECISION ON REQUEST
Hoppe-Seyler, et al.	:	FOR RECONSIDERATION OF
Issue Date: June 9, 2009	:	PATENT TERM ADJUSTMENT &
Application No. 10/519,539	:	NOTICE OF INTENT TO ISSUE
Filed: March 15, 2005	:	CERTIFICATE OF CORRECTION
Attorney Docket No. 085449-0158	:	

This is in response to the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. 1.705," filed January 30, 2009 (and resubmitted August 7, 2009), requesting that the patent term adjustment determination for the above-identified patent be changed from eighty (80) days to eighty-four(84) days.

Patentees request that the decision on this request for reconsideration of patent term adjustment be deferred or delayed until a final decision has been rendered in *Wyeth v. Dudas*. There is no specific regulatory provision for requesting that a petition under 37 CFR 1.705(d) be held in abeyance. Accordingly, the request for deferral/delay of decision under 37 CFR §1.705(d) is **DISMISSED**.

The request for reconsideration of patent term adjustment is **GRANTED** to the extent indicated herein.

The patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of **zero (0)** days.

Patentees are given **THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer**, from the mail date of this decision to respond. No extensions of time will be granted under § 1.136.

Patentees are given **THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer,** from the mail date of this decision to respond. No extensions of time will be granted under § 1.136.

On June 9, 2009, the above-identified application matured into U.S. Patent No. 7,544,768 with a patent term adjustment of 80 days.

This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 1.705(d).

The Office acknowledges submission of the $200.00 fee set forth in 37 CFR 1.18(e). This required fee will not be refunded. No additional fees are required.

Patentees request recalculation of the patent term adjustment based on the decision in *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to *Wyeth*, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), of 256 days and the period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), of 4 days do not overlap as these periods do not occur on the same day.

Patentees argue that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.702(b), is calculated from the application's 371 fulfillment date to the filing of a request for continued examination (RCE).

Patentees are informed that the Three Year Delay period is triggered by the application's commencement date, not the 371 fulfillment date. The commencement date is 30 months from the priority date claimed in the international application, or earlier. The priority date claimed in the international application is July 1, 2002. Patentees did not request early processing under 35 U.S.C. 371 (f). See also § 371(b). Thirty months from that date is January 1, 2005. As January 1, 2005 was a Saturday, January 3, 2005 is the commencement date and is the beginning of the Three Year Delay period. The period is terminated by the filing of a Request for Continued Examination (RCE). The filing of a RCE cuts-off the applicants' ability to accumulate any additional patent term adjustment against the

three-year pendency provision, but does not otherwise affect patent term adjustment. 37 CFR § 1.703(b)(1) However, not all application pendency time is counted toward the Three Year Delay period. See 35 U.S.C. 154(b)(1)(B)(i)-(iii). In this instance, the exclusion in 35 U.S.C. 154(b)(1)(B)(ii) applies. It excludes from the Three Year Delay period any time consumed by appellate review. See also 37 CFR 1.702(b)(4). Therefore, the time consumed by appellate review, the 153 day period running from the date of the filing of the notice of appeal, June 27, 2008, ending on the date the RCE was filed, November 26, 2008, is excluded from the Three Year Delay period.

Accordingly, the period of adjustment due to the Three Year delay by the Office is 175 days (328 - 153 excluded).

Patentees assert that in addition to the three year delay period, they are entitled to a period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a)(1) of 4 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date the application fulfilled the requirements of 35 U.S.C. 371 in an international application.

Under 37 CFR § 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR §1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR §1.704. In other words, the period of Office delay reduced by the period of applicant delay. The period of reduction of 176 days for applicant delay is not in dispute. Patentees assert that the total period of Office delay is the sum of the period of Three Years Delay (256 days per patentees' calculation) and the period of Examination Delay (4 days, not in dispute) **to the extent that these periods of delay are not overlapping.**

Patentees contend that no portion of the two periods of delay overlap.

As such, patentees assert entitlement to a patent term adjustment of 84 days (256 per patentees' calculation +4 reduced by 0 overlap -176 for applicant delay). Considering that the three-year period is properly calculated based on the commencement date with an excluded period due to appellate

review and is 175 days, patentees' assertion of entitlement to a patent term adjustment is considered to be 3 days (175 + 4 reduced by 0 overlap - 176 for applicant delay).

As discussed above, the Office states that the patent issued 3 years and 175 days after the application's commencement date, the calculation of the three year period ending when the November 26, 2008 RCE was filed, and excluding the period consumed by appellate review. The Office agrees that the action detailed above was not taken within the specified time frame, and thus, the entry of period of adjustment of 4 days is correct. At issue is whether patentees should accrue 175 (per Office's calculation of the Three Year Delay Period) days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as, 4 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that the 4 days of the 175 day period for over three year pendency overlap with the 4 days accorded for Office delay prior to the issuance of the patent. Patentees' interpretation of the period of overlap has been considered and found to be incorrect. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

> to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

> To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent

term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

> If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 54366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for

periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3 year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

> Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718[1]

As such, the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the commencement date overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the commencement date of the application. Treating the relevant period as starting on January 4, 2008, the date that is 3 years after the commencement date of the application is incorrect.

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[1] The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period from the application's commencement date to the date of filing of the RCE on November 26, 2008. In addition, 153 days were excluded under 35 U.S.C. 154(b)(1)(B)(ii) as time consumed by appellate review. 4 days of patent term adjustment were accorded prior to the issuance of the patent for the Office failing to respond within a specified time frame during the pendency of the application. The two periods overlap by 4 days.

Therefore, 171 days, not 252 days, of patent term adjustment should have been entered for the Three Year Delay period, since the period of delay of 175 days attributable to the delay in the issuance of the patent overlaps with the adjustments of 4 days attributable to the ground specified in § 1.702(a)(1). Accordingly, considering the overlap, at issuance, 171 additional days should have been entered for the Office taking in excess of three years to issue the patent after the application commencement date. Pursuant to this decision, the entry of 252 days of Office delay is being removed and 171 non-overlapping days of Office delay are now being entered (for a total revised patent term adjustment of 0 days).

In other words, patentees are entitled to a patent term adjustment of 0 days (4 days examination delay +178 days Three Year delay reduced by 4 days overlap - 176 days for applicant delay).

Accordingly, the patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of zero (0) days.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. The Office will issue a certificate of correction indicating that the term of the above-identified patent is adjusted by zero (0) days.

Telephone inquiries specific to this matter should be directed to Shirene Willis Brantley, Senior Petitions Attorney, at (571) 272-3230.

Nancy Johnson
Senior Petitions Attorney
Office of the Deputy Commissioner
for Patent Examination Policy

enclosure: DRAFT certificate of correction

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT : 7,544,768 B2

DATED : June 9, 2009

INVENTOR(S) : Karin Hoppe-Seyler et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by (80) days

Delete the phrase "by 80 days" and insert – by 0 days--